UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION	MDL No. 1592 (MLW) This Document Relates To All Actions

COLUMBIA UNIVERSITY'S CONSOLIDATED REPLY MEMORANDUM IN SUPPORT OF EMERGENCY MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Dated: September 28, 2004

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I. PRELIMINARY STATEMENT

Of all of the plaintiffs, only Johnson & Johnson has it right: "[T]here is no longer a live case or controversy concerning the validity of the '275 patent, and there is no need for further proceedings to determine whether the existing claims of that patent are invalid due to double patenting." Johnson & Johnson ("J&J") Opp. at 1. This should not have been a tough decision for any other plaintiff to make, given the clarity of the Federal Circuit law in this area: "We have held that a covenant not to sue for any infringing acts involving products 'made, sold, or used' on or before the filing date is sufficient to divest a trial court of jurisdiction over a declaratory judgment action." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999).

Notwithstanding a well-developed body of Federal Circuit authority, all of the other plaintiffs argue that one or more of their declaratory relief claims survive for a variety of irrelevant reasons. Most of the plaintiffs argue that the Covenant is insufficient to eliminate a case or controversy because they have continued to engage in research and development activities that use materials and methods that may infringe the '275 patent after the date of the Covenant. The fatal defect with this argument is that Columbia has done absolutely nothing to give plaintiffs any reasonable apprehension of an infringement suit for such future conduct—an essential requirement of subject matter jurisdiction over a declaratory relief claim. To the contrary, Columbia's conduct would give any reasonable party the exact opposite impression: Columbia filed the Covenant to terminate all litigation concerning the '275 patent. Moreover, Columbia has made clear that it does not want to be involved in any litigation over the '275 patent while the Patent Office considers what claims, if any, should emerge from the reissue and reexamination proceedings. As plaintiffs have failed to carry their burden of establishing any

reasonable apprehension of suit for activities after the date of the Covenant, their declaratory relief claims must be dismissed.

Moreover, the declaratory relief claims of three plaintiffs—Biogen, Genzyme, and Abbott—must be dismissed for an additional, related reason: Because the Covenant operated to restore their license agreements, their declaratory relief claims are barred under *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), where the Federal Circuit held that a licensee in good standing has no reasonable apprehension of an infringement suit and, accordingly, no basis to assert declaratory relief claims against the patentee. Indeed, the Court specifically raised the potential impact of *Gen-Probe* during the telephonic hearing conducted on September 9 as a further reason that Columbia should apprise each plaintiff as to whether the Covenant resulted in the reinstatement of its license agreement. Having done so, Columbia now requests that the Court dismiss the declaratory relief claims of these three plaintiffs on this alternative and independent ground.

Plaintiffs' other attempts to manufacture a case or controversy are equally meritless. Plaintiffs argue that the Covenant must cover their affiliates and subsidiaries; that the Covenant must cover product lines that may be sold in the future to a non-plaintiff; and that the Covenant must cover claims in the '159 application that plaintiffs contend are the same as or substantially identical to claims in the '275 patent as it currently reads. This wish list of additional protections may be desirable from plaintiffs' perspective, but it has nothing whatsoever to do with subject matter jurisdiction, the only issue before this Court. Plaintiffs cite no authority—and there is none—suggesting that any of these expansions of the Covenant is required to eliminate an actual, present case or controversy between Columbia and plaintiffs concerning the validity, enforceability, or infringement of the '275 patent.

Finally, all plaintiffs argue at length that the Court retains jurisdiction over their attorneys' fees claims under 35 U.S.C. § 285. On the other hand, no plaintiff ever explains how it possibly could be a "prevailing party"—a requirement to recover attorneys' fees under section 285—in light of the Supreme Court's decision in *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't. of Health & Human Resources*, 532 U.S. 598 (2001). There, the Supreme Court held that a "prevailing party" under federal fee-shifting statutes must "receive at least some relief on the merits" from the court. *Id*. at 603. Plaintiffs will have received no relief from this Court on the merits. Quite to the contrary, their declaratory relief claims will be dismissed for lack of subject matter jurisdiction as a result of voluntary steps taken by Columbia. Accordingly, their attorneys' fees claims should be dismissed.[1]

II. ARGUMENT

A. The Covenant Eliminates Any Case or Controversy Over Plaintiffs' Declaratory Judgment Claims

The parties appear to agree that the Covenant eliminates any case or controversy with respect to any products made, used, sold, offered for sale, or imported by plaintiffs on or before September 1, 2004. Moreover, the parties also appear to agree that the products covered by the Covenant include intermediate tools used in the course of developing a commercially viable cell line, such as DNA constructs used to produce cotransformed cells and cotransformed cells themselves, as well as cotransformed cells that have expressed proteinaceous material or a

[1] As outlined in Appendix 1 to Columbia's moving papers, Columbia seeks dismissal of all of the plaintiffs' claims, with the exception of Genentech's fifth claim for relief and Columbia's counterclaims against Amgen and Immunex. As J&J notes in its opposition memorandum, events subsequent to the filing of the Motion to Dismiss have removed any case or controversy as to its fifth claim for relief. *See* J&J Opp. at 3.

glycoprotein of interest.[2] Plaintiffs argue, however, that there is still an actual case or controversy because, after September 1, 2004, they have continued their research and development efforts to build new DNA constructs, transform new cells, and express new proteins of interest.

Plaintiffs are wrong. Under the two-part test for the existence of an actual case or controversy, plaintiffs have the burden of establishing both:

> (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995). While plaintiffs argue at length that they are taking concrete steps to conduct infringing activity, they fail to establish that they have any reasonable apprehension of an infringement suit for such activity.

"Factors or circumstances frequently relied upon [as giving rise to a reasonable apprehension of an infringement suit] include (1) a history of litigation between the same two parties, (2) threats or statements to customers, (3) a suit against a customer, (4) suits against others based on a broad interpretation of a patent, (5) a general announcement published in a

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[2] Biogen and Genzyme suggest that the '275 patent does not cover the commercial product itself. Biogen Opp. at 20. That statement is highly misleading. It is true that the claims of the '275 patent do not recite an expressed protein in finished pharmaceutical form. But the claims do recite the expressed protein within the cotransformed cell. For example, claim 19 states: "The transformed Chinese Hamster Ovary cell of any of claims 16-18, *further comprising the glycoprotein of interest*." (emphasis added). Thus, the '275 patent does cover the therapeutic proteins that plaintiffs manufacture. Nor is it true that the '275 patent "is infringed, if at all, during the research and development process." Biogen Opp. at 20. For example, claim 19 of the '275 patent would be infringed whenever a company has a Chinese Hamster Ovary cell of any of claims 16-18 that has expressed a glycoprotein of interest. That could take place either during the research and development process or during commercial manufacturing.

trade paper, (6) an opinion of counsel for the patent owner, (7) assertions made during license negotiations or arbitration, and (8) suits abroad on analogous foreign patents." 8 *Chisum on Patents* § 21.02[1][d][iii][A], at 21-83 to 21-87 (updated 2004). Moreover, reasonable apprehension of suit must be based on events that occurred at the time the declaratory judgment action was filed, not on events that occurred after the filing of that action. *See Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 635 (Fed. Cir. 1991), partial abrogation on other grounds recognized by *Liquid Dynamics Corp. v. Vaughan Co., Inc*., 355 F.3d 1361, 1370 (Fed. Cir. 2004) ("We agree wholeheartedly that in personam and subject matter jurisdictional facts must be pleaded, and proved when challenged, and that later events may not create jurisdiction where none existed at the time of filing."); *West Interactive Corp. v. First Data Resources, Inc*., 972 F.2d 1295, 1297 n.* (Fed. Cir. 1992) ("Because this court examines West's declaratory judgment action at the time of its filing, First Data's subsequent action [filing infringement suit against West] is irrelevant.").[3]

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[3] *See also Waters Corp. v. Hewlett-Packard Co.*, 999 F. Supp. 167, 171 (D. Mass. 1998) ("the court must examine the facts existing at the time the complaint is filed to determine whether an 'actual controversy' existed at that time"); *Bausch & Lomb Inc. v. Ciba Corp.*, 39 F. Supp. 2d 271, 273 (W.D.N.Y. 1999) ("test is to be applied to the facts as they existed at the time the complaint was filed"); *Progressive Technology in Lighting Inc. v. Lumatech Corp.*, 45 U.S.P.Q.2d 1928, 1933 (W.D. Mich. 1998) (Plaintiff "simply may not rely on after-occurring events to demonstrate the existence of subject matter jurisdiction."); *CAE Screenplates, Inc. v. Beloit Corp.*, 957 F. Supp. 784, 789-90 (E.D. Va. 1997) ("*all* facts learned by plaintiff subsequent to the commencement of the declaratory judgment suit should be accorded no weight in the jurisdictional calculus"); *Ryobi America Corp. v. Peters*, 815 F. Supp. 172, 174 (D.S.C. 1993) (Plaintiff "can not 'bootstrap' jurisdiction by relying on [post-filing] statements"); *Performance Abatement Services, Inc. v. GPAC, Inc.*, 733 F. Supp. 1015, 1019 (W.D.N.C. 1990) ("The Court believes that [plaintiff] cannot attempt to justify its claimed apprehension on factors that occurred after [plaintiff] filed this action."); *Millipore Corp. v. University Patents, Inc.*, 682 F. Supp. 227, 231 (D. Del. 1987) ("Activities that occurred subsequent to the filing of the Complaint may not be considered since jurisdiction, if it exists, must be established as of the date of the filing of the declaratory judgment action.")

Plaintiffs provide no evidence that Columbia has done any of these things, as there is none. The only pre-suit conduct on which any plaintiff relies is two letters that are nearly two years old and do nothing more than announce the issuance of the '275 patent and state Columbia's then-existing position that additional royalties were owed under the Axel family of patents. Biogen Opp. at 18. These letters do not create any reasonable apprehension that Columbia would file an infringement suit two years later. *See Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992) (no reasonable apprehension of suit where Amoco had informed Shell that its activities "fall within" Amoco's patent and Amoco's attorney later responded "yes" when asked whether Amoco intended to enforce its patent); *Charles Machine Works, Inc. v. Digital Control Inc.*, 264 F. Supp. 2d 980, 986 (W.D. Okla. 2003) ("The only direct communications between the parties in this case concerning patent issues occurred in 1997 and 1998. Those communications provided no basis for CMW to fear litigation by DCI in 2002, both because of their remoteness in time and because nothing that DCI said suggested an intent to pursue patent infringement litigation."); *Kustom Signals, Inc. v. Applied Concepts, Inc.*, No. 96-2274-JWL, 1996 WL 568817, at *6 (D. Kan. Sept. 16, 1996) (dismissing declaratory relief action for no reasonable apprehension of infringement where patentee sent letter that "does no more than announce the allowance of ACI's patent, suggest that competitors using the technology covered by the patent obtain a license, and invite license negotiations.").[4] Moreover,

[4] *See also Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, No. Civ. A. 03 CV 10167 RGS, 2003 WL 22888848, at *4 (D. Mass. Dec. 8, 2003) (no reasonable apprehension of suit where "(1) Pfizer has listed [the patent] in the Orange Book; (2) Pfizer has refused to grant Teva a covenant not to sue; (3) Pfizer has aggressively asserted its patent rights against alleged infringers of other of its patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it is in Pfizer's self-interest 'to leave a cloud of litigation' hanging over Teva as a means of protecting Ivax's 180-day exclusivity period.").

as Columbia has now made very clear to Biogen and the other plaintiffs, no royalties are currently owed under the '275 patent.

In addition, even if post-filing actions were relevant for jurisdictional purposes, there can be no actual controversy because Columbia has done nothing that would create a reasonable apprehension of suit for infringement as to any activities following the date of the Covenant. To the contrary, at the most recent hearing in this litigation, conducted telephonically on September 9, Columbia's counsel communicated that Columbia has no desire to litigate the '275 patent while the Patent Office is considering what claims of that patent, if any, deserve protection under the patent laws. *See* Ex. A to Gindler Decl. (Tr. of Sept. 9, 2004 Hearing at 33:8-14) (decision to file the Covenant "was largely driven by the university's desire not to litigate [the] '275 patent while the Patent Office is determining what if any patent rights Columbia is entitled to have in the first place").

Plaintiffs claim that the letters from Columbia's counsel regarding the scope of the Covenant include "threatening statements." *See, e.g.*, Biogen Opp. at 18. They do not. The letters simply respond—clearly and directly—to questions that plaintiffs themselves posed to Columbia as to the scope of the Covenant. Columbia answered these questions (at the specific direction of the Court) in the hope of eliminating a case or controversy, not creating one, by assuring plaintiffs that all of their pre-September 1 products, whether described as DNA constructs, cotransformed cells, or therapeutic proteins of interest, are covered by the Covenant. Plaintiffs have no basis to describe these letters as "threatening."

Nor does the Covenant itself, as Biogen and Genzyme claim, create a reasonable apprehension of suit as to post-September 1 activities. *See* Biogen Opp. at 17. Indeed, the Covenant demonstrates just the opposite. The very purpose of the Covenant is to *terminate*

litigation over the '275 patent, not to threaten it. Columbia's counsel made very clear at the September 9 telephonic hearing that Columbia filed the Covenant to allow the Patent Office to rule upon the reissue application before there is any further litigation over the '275 patent. Columbia has thus clearly communicated to plaintiffs that it will not sue them for infringement of the '275 patent—as to any product—at any time while the Patent Office is considering the reissue application and the reexamination petition. In the absence of any real and immediate threat, plaintiffs have no reasonable apprehension of an infringement suit based on any activities that occur after the filing of the Covenant. *See Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (to establish subject matter jurisdiction, declaratory judgment plaintiff must show a "substantial controversy . . . of *sufficient immediacy and reality* to warrant the issuance of a declaratory judgment") (emphasis added); *see also Leatherman Tool Group Inc. v. Bear MGC Cutlery Inc.*, 50 U.S.P.Q.2d 1856, 1858 (D. Or. 1998) ("Bear's willingness to forego [filing a legal] action confirms my conclusion that Leatherman does not have a reasonable apprehension of suit at this time. I accept Bear's representation that it will not sue during the twelve month period" following the hearing on Bear's motion to dismiss).[5]

[5] Biogen and Genzyme suggest that Columbia has sought to delay proceedings in the Patent Office by requesting a stay of the reexamination petition in light of the reissue application, instead of seeking a merger of the two procedures. Biogen Opp. at 7-8. Quite the opposite is true. Columbia believes that the entire process in the Patent Office will be expedited by a review of the reissue application and a stay of the reexamination. This is because the issues raised by the reexamination petition will be addressed in the course of the reissue proceeding. As Columbia stated in its Petition to Stay Ex Parte Reexamination filed in the Patent Office: "In addition, the issues in the subject reexamination and in the reissue are, or are anticipated to be, overlapping and to relate to the question of obviousness-type double patenting over Patentee's previously issued patents which derive from the continuation applications which have the same ultimate parent as the '275 Patent. All such issues will be resolved in the application for reissue." Petition at 4 (Tab 23 to Levy Declaration). In such circumstances, Patent Office procedure provides for a stay of the reexamination in favor of the reissue proceeding. In short,

Moreover, while plaintiffs suggest otherwise, the Covenant contains no threats about plaintiffs' future activities or products. It simply states which products are within the scope of Columbia's promise not to sue, without in any way mentioning future products or activities. It is true that the Covenant includes a brief statement intended to communicate that Columbia does not concede the merits of *any of plaintiffs' claims.* Covenant at 1 ("Columbia in no way concedes that the '275 patent is not infringed, invalid, or unenforceable . . . and categorically rejects *all such claims by plaintiffs*.") (emphasis added). Columbia included this statement to make clear to plaintiffs and to the Court that Columbia is not conceding defeat in these actions—nothing more, nothing less. Columbia's denial of the merits of plaintiffs' claims says nothing about whether Columbia plans to take any action at any time in the future against any plaintiff's post-September 1 activities.

All of the other facts that plaintiffs claim create a reasonable apprehension of suit involve conduct that occurred *before* the filing of the Covenant. That conduct is irrelevant to the issue of whether Columbia has done something to create a reasonable apprehension that it will sue plaintiffs for activities that take place *after* the filing of the Covenant. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) ("Although an actual controversy may have existed before Quadlux filed its covenant not to assert a patent infringement claim against Amana, it is not necessary for us to address that issue. '[A]n actual controversy must be extant at all stages of review, not merely at the time the complaint is filed,' and it is clear that no

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Columbia believes that the Patent Office will move much more quickly if there is just one proceeding instead of two.

controversy survives the Quadlux covenant.") (internal citation omitted).[6] Columbia has done nothing since the filing of the Covenant to create any reasonable apprehension of an infringement suit under the '275 patent for any activities occurring after September 1, 2004.

Even if one were to consider all of the other conduct mentioned by plaintiffs, irrespective of when it took place, none of that conduct comes close to creating any reasonable apprehension of suit as to plaintiffs' activities after the filing of the Covenant. Although Columbia's counsel briefly stated at the June 22 hearing (when responding to questions from the Court) that there likely would be some infringement counterclaims, nothing was said about which licensees would be sued or for which products. Columbia's counsel did not make any statements concerning the breadth of the claims of the '275 patent, or the particular products or activities that would infringe those claims. In any event, Columbia's defense of plaintiffs' declaratory relief claims with respect to the validity and infringement of its patent do not constitute a threatened infringement suit. *Shell Oil*, 970 F.2d at 889 (in affirming dismissal of declaratory relief claims for lack of subject matter jurisdiction, court held that when "Amoco . . . defended its patent. . . . it should not be considered to have threatened Shell with suit").[7]

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[6] *See also Hewlett-Packard Co. v. Genrad, Inc.*, 882 F. Supp. 1141, 1156 (D. Mass. 1995) (because "HP's assurances [in an April 1994 letter and June 1994 hearing that it would not sue Genrad on a certain product] diminish the effect of its conduct at the September 21, 1993 meeting," at which HP threatened "dire consequences" if Genrad continued to sell that product, Genrad "fail[ed] to meet its burden" of showing an actual controversy, even though Genrad had improved that product after the September 1993 meeting).

[7] Biogen and Genzyme also refer to several pages from Columbia's previous briefing in this litigation to support their allegation that "Columbia repeatedly stated . . . that it will likely sue the plaintiffs for infringement." Biogen Opp. at 18 n.9. A review of each of those pages reveals only hypothetical statements as to what "may" occur "if" certain other potential events actually transpire. In these previous briefs, Columbia merely noted what *could* happen during the course of the litigation. Columbia never at any time threatened that an infringement suit was likely.

Nor has Columbia brought "infringement claims" against any other licensees of the '275 patent, as Biogen and Genzyme assert. Biogen Opp. at 18. Columbia brought breach of contract and declaratory relief claims against J&J and Serono, which have been dismissed, and against Amgen and its subsidiary Immunex, which relate to liability for substantial royalties owed under the predecessor Axel patents.[8] None of those claims contains any infringement allegations whatsoever, or any other language that would suggest that Columbia plans to assert the '275 patent against any plaintiff's activities.

Finally, Columbia hardly could be characterized as a frequent purveyor of litigation over the Axel family of patents. Prior to the current disputes over the '275 patent, Columbia had filed only two actions alleging infringement of an Axel patent, one of which resulted in an infringement verdict,[9] and the other of which was dismissed not long after it was filed.[10]

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[8] Although Columbia's counterclaims against Amgen do not provide detailed facts concerning the parties' contractual dispute, the major issue between the parties relates to Amgen's refusal to pay royalties under the predecessor Axel patents (not the '275 patent) for products made before, but sold after, the expiration of those patents. All other licensees have paid royalties on such products. The counterclaims against Amgen make no mention of the '275 patent or of royalties specifically owed under that patent, and in light of the Covenant, Columbia will not use the counterclaims to pursue any claim for relief against Amgen relating to the '275 patent.

[9] *See* Ex. B to Gindler Decl. (opinion in *The Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, C.A. No. 93-11512-NG (D. Mass. Sept. 30, 2002)).

[10] *See* Ex. C to Gindler Decl. (docket for *The Trustees of Columbia University in the City of New York v. Genetics Institute, Inc.*, No. 90cv677, filed in the District of Delaware on November 20, 1990 and closed November 12, 1991).

In short, plaintiffs have failed to carry their burden of showing any reasonable apprehension that they will be sued for infringement based on their activities after the filing of the Covenant. The Court should thus dismiss all of their declaratory relief claims.[11]

B. *Gen-Probe* Requires Dismissal Of The Declaratory Judgment Claims Brought By Biogen, Genzyme, And Abbott Because Licensees In Good Standing Have No Reasonable Apprehension Of Suit

Columbia has withdrawn the notices of termination previously sent to Biogen, Genzyme, and Abbott and has informed them that their license agreements are in full force and effective retroactive to the date on which they otherwise would be terminated. Under *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), as licensees in good standing, they cannot have a reasonable apprehension that they will be sued for infringement of the licensed patent.[12]

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[11] Wyeth argues that the Court should allow the declaratory relief claims relating to prosecution laches and inequitable conduct to proceed because a finding in plaintiffs' favor "would render moot the reissue and reexamination proceedings." Wyeth Opp. at 7. The Federal Circuit has squarely held, however, that such ongoing proceedings in the Patent Office do not create an actual controversy sufficient to support subject matter jurisdiction over a declaratory relief claim. *See Spectronics*, 940 F.2d at 636 (while reissue application is pending, there is no actual controversy because there is "no guarantee that the reissue patent will eventually issue…[and] no reissue claims yet exist by which infringement *vel non* can be measured"); *Amana*, 172 F.3d at 856 ("Here, as in *Spectronics*, the future existence of a reissue patent is wholly speculative and, therefore, cannot create a present controversy.").

[12] While plaintiffs suggest otherwise, it is untrue that issues concerning the *Gen-Probe* case were raised with plaintiffs for the first time in Columbia's letter dated September 20, 2004. Indeed, quite to the contrary, during the September 9 telephonic hearing, the Court itself raised *Gen-Probe* when explaining the reasons why Columbia, during the meet-and-confer process, should inform each plaintiff as to whether its license agreement remains terminated in light of the Covenant. As the Court explained at the telephonic hearing:

> THE COURT: Well, that anticipated my next question. These are the type of things when, you know, you're conferring, to narrow or eliminate disputes, you ought to be focusing on, because if Biogen has its license back, if it's Columbia's position—and it has to be clarified that it's not terminated—under that Gen-Probe case that I discussed at 29 to 30 of [my] preliminary injunction decision on August 13, *maybe that contributes to eliminating a case [or] controversy too*.

The facts and reasoning of *Gen-Probe* are instructive. After entering into a license agreement with respect to the '338 patent, Gen-Probe filed an action against Vysis, the patentee, alleging that it did not infringe the patent and that the patent is invalid and unenforceable. Gen-Probe paid all royalties owed under the license agreement and remained a licensee in good standing during the litigation. Vysis filed a motion to dismiss the action for lack of subject matter jurisdiction on the ground that, "as a licensee in good standing, Gen-Probe could not have had a reasonable apprehension of suit when it initiated this action." *Id.* at 1379. The district court denied the motion. *Id.*

The Federal Circuit reversed. The court began by observing that declaratory relief jurisdiction requires "a reasonable apprehension on the part of the declaratory relief plaintiff that it will face an infringement suit." *Id.* at 1380. The court observed that Gen-Probe could not have any reasonable apprehension because "the license insulated Gen-Probe from an infringement suit instituted by Vysis." *Id.* at 1381. Accordingly, the court concluded that "[t]his license, unless materially breached, obliterated any reasonable apprehension of a lawsuit based on the prior circumstances cited by the district court for jurisdiction." *Id.*

Ex. A to Gindler Decl. (Tr. at 9:5-13) (emphasis added). Thus, the Court made clear that one purpose of the additional meet-and-confer time was to allow Columbia to clarify the status of plaintiffs' license agreements so that the parties could address whether "that contributes to eliminating a case [or] controversy." As the Court requested, Columbia provided written notice to plaintiffs of the status of their license agreements on Monday, September 13, nine days before their oppositions to the Motion to Dismiss were due. Furthermore, while under no obligation to do so, on September 20, Columbia also sent letters to Biogen, Genzyme, and Abbott, stating Columbia's (unsurprising) position that no case or controversy exists as to these plaintiffs under *Gen-Probe*. As the Court can see by comparing Columbia's September 20 letter with Section II.B. of this Reply, Columbia surfaced all of its arguments in that letter.

The present case is no different. The license agreements of Biogen, Genzyme, and Abbott are in full force and effect. Under *Gen-Probe*, these license agreements "obliterate[] any reasonable apprehension of a lawsuit" for infringement of the '275 patent.

Moreover, Columbia's Covenant further secures Biogen and Genzyme's freedom from apprehension of imminent legal action by Columbia. The *Gen-Probe* court expressly noted that a valid license agreement amounts to "an enforceable covenant not to sue." *Id*. at 1381. Accordingly, in light of the Covenant and Columbia's recent confirmation that these plaintiffs' license agreements are in full force and effect, they enjoy the protection of two separate barriers between them and any reasonable fear of infringement litigation. Thus, as in *Gen-Probe*, there is no basis for continued exercise of subject matter jurisdiction over these plaintiffs' declaratory judgment claims.

While Columbia did inform these plaintiffs that, by withdrawing its termination of their licenses, Columbia is not waiving any grounds for termination other than those relating to the '275 patent, it did so merely to preserve its rights as to any grounds for termination that are currently unknown but may emerge at a later date (such as a failure to pay all royalties owed under the predecessor Axel patents). At the present time, however, Columbia knows of no grounds for termination of the licenses of Biogen, Genzyme, or Abbott. Each of these plaintiffs has continued to pay the annual maintenance fee required to keep its license in force.

Accordingly, these plaintiffs have no apprehension of suit—reasonable or otherwise—and their declaratory judgment claims must be dismissed.[13]

C. The Covenant's Exclusion Of The '159 Application Has No Bearing On Whether A Present Controversy Exists

Plaintiffs' position with respect to the '159 application directly conflicts with controlling Federal Circuit authority. As Columbia noted in its moving papers, subject matter jurisdiction cannot be based on a hypothetical future scenario which *could* give rise to an infringement claim. *See Spectronics*, 940 F.2d at 636 (noting, in the context of reissue proceedings, that there is no present controversy because there is "no guarantee that the reissue patent will eventually issue…[and] no reissue claims yet exist by which infringement *vel non* can be measured"). In *Spectronics*, the Federal Circuit explained that "[b]efore a patent issues, and *during the pendency*

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[13] Biogen and Genzyme suggest that Columbia could terminate their licenses because they have failed to provide quarterly reports since 2002. Biogen Opp. at 25. This is nonsense. Failure to provide quarterly reports was included as a basis for termination in the notice letters because Biogen and Genzyme were required to provide such reports showing the amount of royalty due each quarter under the '275 patent. Because the only royalties that Biogen and Genzyme have failed to pay are those that otherwise would have been due under the '275 patent, and because Columbia has relieved Biogen and Genzyme of any obligation to pay royalties under the '275 patent with respect to products covered by the Covenant, Biogen and Genzyme cannot be in breach of their license agreements for failure to provide quarterly reports. These plaintiffs have no obligation to provide royalty reports for periods when no royalties are due. Columbia rejects any interpretation of the license agreements to the contrary, and will never terminate plaintiffs' licenses for failing to provide quarterly reports for periods when no royalties are due.

In addition, Biogen, Genzyme, and Abbott argue that Columbia has never previously contested whether subject matter jurisdiction exists over their cases. This is untrue, as Columbia's answer to their complaint asserts lack of subject matter jurisdiction as an affirmative defense. *See* Columbia's Answer to Amen. Compl. of Biogen, Genzyme, and Abbott at ¶ 78 (Second Affirmative Defense: "The Court lacks subject matter jurisdiction over the Amended Complaint and each of its purported claims."). It is also irrelevant, however, as lack of subject matter jurisdiction is a defense that can never be waived. *See Grupo Dataflux v. Atlas Global Group, L.P.*, 124 S. Ct. 1920, 1924 (2004) ("Challenges to subject-matter jurisdiction can of course be raised at any time prior to final judgment.").

of a patent application in the PTO, the courts have no claims by which to gauge an alleged infringer's conduct. Before issuance, what the scope of claims will be is something totally unforeseeable." 940 F.2d at 636-37 (citation and quotations omitted) (emphasis added). Accordingly, the court rejected the argument that a pending reissue application is sufficient to create an actual controversy to support subject matter jurisdiction. *Id*. at 636. The Federal Circuit reached the same conclusion in *Amana*. 172 F.3d at 856 ("Here, as in *Spectronics*, the future existence of a reissue patent is wholly speculative and, therefore, cannot create a present controversy.").

Spectronics and *Amana* are not the only cases directly on point. In *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479 (Fed. Cir. 1996), a case fleetingly mentioned by Amgen and no other plaintiff, the Federal Circuit held that there was no "justiciable case or controversy" as to a complaint that "alleged a dispute over the validity and infringement of a possible future patent not then in existence." *Id*. at 482. Because the dispute as to a pending patent application "was purely hypothetical and called for an impermissible advisory opinion," the Federal Circuit held that exercise of subject matter jurisdiction over the declaratory judgment claims was improper. *Id*.

Plaintiffs argue that because Columbia has clarified that the Covenant applies to any claim in any reissue of the '275 patent that is the same as or substantially identical to a claim of the '275 patent as it currently reads, Columbia must extend the Covenant to any such claims in the pending '159 application. While plaintiffs may desire this expansion of the Covenant, it is not required to eliminate an actual case or controversy. As discussed above, there can be no case or controversy over whether a declaratory judgment plaintiff infringes a claim in a pending patent application.

When Columbia clarified that the Covenant covered any reissue patent claims that are identical to any original '275 patent claims, Columbia was not expanding the scope of the Covenant. Rather, it was describing the legal consequence of the Covenant under *Spectronics*. There, the Federal Circuit rejected Spectronics' contention "that it could be held liable for its current allegedly infringing activities if any of the reissue claims are 'identical' to the original claims" of the patent covered by the defendant's covenant not to sue. 940 F.2d at 637.

The case law could not be more straightforward: Fear of litigation over claims that *might* issue *at some point* from a pending patent application is insufficient to constitute an actual controversy to support a declaratory relief claim. Thus, it is irrelevant that the Covenant does not extend to the claims of the '159 application for resolution of the jurisdictional issue before this Court.[14]

D. The Covenant's Exclusion Of Affiliates Or Subsidiaries Is Irrelevant To This Motion To Dismiss

Biogen, Genzyme, and Abbott suggest that there is an actual controversy sufficient to support subject matter jurisdiction because the Covenant does not extend to their respective affiliates or subsidiaries. This argument is a red herring. The jurisdictional question at the core of this motion relates only to whether there is a case or controversy between Columbia and the *plaintiffs*, not their corporate relatives. No subsidiary or affiliate of Biogen, Genzyme, or Abbott is a party to this action. Even assuming that (1) an affiliate of one of the plaintiffs is engaged in infringing activity, and (2) Columbia had made an explicit threat or taken other action such that

[14] Columbia disagrees with Amgen's argument that there are claims in the '159 application that are the same as or substantially identical to claims in the '275 patent. Amgen Opp. at 7-12. We do not address this argument, however, because Columbia simply has no obligation to extend the Covenant to any claims in the '159 application in order to eliminate an actual controversy to sustain subject matter jurisdiction over a declaratory relief claim.

the affiliate reasonably feared a lawsuit (Columbia has taken no such action), there would still be no case or controversy *in this litigation between Columbia and the plaintiffs.* The fact that the Covenant does not extend to Biogen, Genzyme, and Abbott's affiliates may be disappointing to these plaintiffs from a business standpoint, but it is irrelevant to this Court's evaluation of the jurisdictional issue. Plaintiffs cite no authority in support of their position, as there is none.

Abbott's complaint that the Covenant cannot be assigned to a third party who may acquire a covered product in the future is similarly unavailing. Abbott asserts that this Court retains jurisdiction over its declaratory judgment claims because "if [Abbott] is to transfer the HUMIRA® asset to another corporate entity, even within the Abbott corporate family, the Covenant…would not transfer with the HUMIRA® asset." Abbott Opp. at 7. Abbott's concerns are simply immaterial to the jurisdictional issue. Abbott cites no authority in support of its position, and no case has ever held that a covenant not to sue must be expanded in such a way to defeat subject matter jurisdiction. Moreover, the harm that Abbott fears is purely hypothetical and thus insufficient to constitute an actual case or controversy. *See Amana*, 172 F.3d at 855 (no actual controversy as to possible future events).

E. There Is No Case Or Controversy As To Wyeth's Claims "Related To Columbia's Oppressive Licensing Tactics"

Wyeth alleges that certain of its claims should survive this Motion to Dismiss, but it fails to address the logical implications of such a scenario. If this Court were to retain jurisdiction over Wyeth's Seventh, Eighth, and Ninth Claims, as Wyeth argues that it should, and if Wyeth were to prevail on these claims, the "relief" it would receive would be the very same relief already provided to Wyeth by the Covenant—freedom from enforcement of the '275 patent and royalty obligations.

Wyeth's Seventh Claim requests a declaration that the '275 patent is unenforceable. Wyeth Compl. at ¶¶ 87-93. The Covenant already affords Wyeth freedom from enforcement of the '275 patent. Wyeth's Eighth Claim seeks a "royalty-free license." *Id*. at ¶¶ 97-98. The Covenant has now given Wyeth a promise that it will not be sued for royalties on the '275 patent as it presently reads. Similarly, Wyeth's Ninth Claim requests a declaration that no royalties are owed on the '275 patent. *Id.* at ¶¶ 101-104. The Covenant already provides this assurance.[15]

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[15] Wyeth argues that its complaint also alleges that Columbia improperly terminated the parties' license agreement. Wyeth Opp. at 2. There is no such claim or allegation anywhere in Wyeth's complaint. Wyeth also argues that it overpaid Columbia nearly $2 million in royalties under the predecessor Axel patents. Wyeth Opp. at 11. This specific allegation is also found nowhere in Wyeth's complaint. In any event, as Columbia understands it, this issue relates to whether a particular product (ReFacto) is covered by a European Axel patent, not the '275 patent. In addition, while it is true that Wyeth's complaint seeks a declaration that it owes no fees to Columbia, that claim is irrelevant to the validity, enforceability, or infringement of the '275 patent. The annual fee is not a royalty based on the '275 patent; it is a maintenance fee that is owed each year during the term of the license agreement. *See* Ex. D to Gindler Decl. at Section 3(b) ("On the first day of January of each calendar year following 1990, Licensee shall pay Columbia a non-refundable annual fee of $30,000."). Wyeth last paid this annual maintenance fee in 2001, even though the agreement licensed another patent, the '636 patent, that does not expire until 2009. *See* Ex. E to Gindler Decl. ("'Licensed Patent Rights' means…any and all divisions, continuations and continuations-in-part based on" patent applications, including Application No. 249,454 (which eventually issued as the '636 patent)); Ex. F to Gindler Decl. Some licensees, such as Abbott, Genzyme, and Biogen have elected to pay all annual fees to keep their licenses in place; others, such as Wyeth, have not.

Wyeth also argues that Columbia withdrew its termination of the parties' license agreement, but subsequently terminated the license agreement again on a different ground. Wyeth Opp. at 4, 11. This is incorrect. Columbia sent a notice of termination to Wyeth on March 9, 2004, setting forth several grounds for termination. *See* Ex. G to Gindler Decl. One ground was the failure to pay royalties; another ground was the failure to pay all annual fees required by the license agreement. In a letter to the Court dated September 3, 2004, Columbia acknowledged that the notices of termination previously sent to plaintiffs were ineffective to the extent that they were based on the failure to pay royalties on account of the '275 patent. Ex. H to Gindler Decl. That letter did not reinstate Wyeth's license agreement; it simply acknowledged the withdrawal of one of several grounds for the termination of that agreement. On September 13, 2004, Columbia sent a letter to Wyeth confirming that its license agreement was still terminated on account of Wyeth's failure to pay all annual fees. Wyeth does not contest that it has failed to pay these fees.

While Wyeth may desire protection as to activities it would like to undertake in the future, the Covenant destroys any *present* controversy as to enforcement of the '275 patent and Wyeth's royalty obligations. Thus, contrary to Wyeth's assertion that its "contract claims remain within this Court's jurisdiction," these claims must be dismissed because there is no additional relief this Court could grant. *See Oakville Development Corp. v. FDIC*, 986 F.2d 611, 615 (1st Cir. 1993) (dismissing appeal as moot where no relief the court could grant would change the present circumstances because "for us to pronounce judgment in the absence of any effective remedy would be to wander impermissibly into the realm of the advisory and the hypothetical").

F. There Is No Dispute With J&J Over Royalties Owed On The '275 Patent

J&J's assertion that Columbia "has not relinquished its claim for a $500,000 annual 'minimum royalty'" related to the '275 patent under the parties' 1989 license agreement is no longer correct. *See* J&J Opp. at 2. Columbia has recently assured J&J that it owes *nothing* to Columbia on the '275 patent under the 1989 license agreement (which covers a single product, erythropoietin) unless and until the Patent Office issues a reissued version of that patent with claims that are not the same as or substantially identical to original claims of the '275 patent. *See* Ex. I to Gindler Decl. Accordingly, there is no dispute between Columbia and J&J as to whether any royalties are owed under the 1989 license agreement based on the '275 patent as it currently reads.

G. No Controversy Exists With Respect To Genentech's Past Royalty Payments

Genentech argues that its right to recover a single royalty payment that it claims it made on the '275 patent gives rise to an actual controversy. Assuming that Genentech can confirm to Columbia that this one payment was specifically for its use of the '275 patent, Columbia agrees

to return that payment to Genentech, thereby eliminating any controversy, and permitting the dismissal of Genentech's declaratory judgment claims.

H. The Duplicative, And Improperly Filed, Complaint That Biogen And Genzyme Recently Filed In Violation Of Federal Rule Of Civil Procedure 15 And This Court's Express Instructions Should Be Disregarded

Well aware that the declaratory relief claims in this action will be dismissed for lack of subject matter jurisdiction, Biogen and Genzyme have committed an outrageous procedural violation. Instead of seeking leave to amend their complaint, they have filed a second, duplicative lawsuit in this District, which repeats all of the allegations of their complaint in this action—including the declaratory relief claims over which the Court lacks subject matter jurisdiction—along with four new claims for relief and one new party (Biogen's parent corporation). Biogen and Genzyme filed that duplicative action even though the Court made very clear to their counsel at the September 9 telephonic hearing that, if they desired to add new claims, they must file a motion seeking leave to do so: "Well, you'd have to move for leave to amend it, and then I'd have to decide if that's contested and, if it's contested, whether the interests of justice make it appropriate." Ex. A to Gindler Decl. (Tr. at 20:13-16).

This is a transparent effort to evade the requirements of Rule 15 of the Federal Rules of Civil Procedure. If Biogen and Genzyme desire to amend or supplement their complaint, they must seek leave from this Court *before simply filing their amended pleading*. They are not entitled to the self-help remedy of filing a duplicative action containing their desired amendments. Biogen and Genzyme must explain the grounds for the amendment and establish that the proposed claims for relief are timely, non-prejudicial, and would not be futile. *See, e.g., In re Stone & Webster, Inc., Securities Litig.*, 217 F.R.D. 96, 98 (D. Mass. 2003) ("A district court's decision to deny leave to amend, pursuant to rule 15(a), will not be found to be an abuse

of its discretion where there appears to be an adequate reason for the denial of leave to amend (e.g., undue delay, bad faith, dilatory motive, futility of amendment, prejudice[.])") (quotations omitted). Biogen and Genzyme must also establish that allowing the amendment at this time would serve the interests of justice. Fed. R. Civ. P. 15(a). They have made no attempt to comply with any of these requirements.[16]

Biogen and Genzyme appear to suggest that because the newly asserted claims relate to occurrences "that have happened since the date of pleading" in this case, these claims "are properly considered by the Court within the context of this case," even though they failed to seek

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[16] *Friends of the Earth, Inc. v. Crown Central Petroleum Corp.*, 95 F.3d 358, 362 (5th Cir. 1996) ("When a plaintiff files a second complaint alleging the same cause of action as a prior, pending related action, the second complaint may be dismissed. . . . This rule finds particular application where, as here, the plaintiff files the second complaint to achieve procedural advantage by circumventing the rules pertaining to the amendment of complaints.") (quotations omitted); *Finch v. Hughes Aircraft Co.*, 926 F.2d 1574, 1577 (Fed. Cir. 1991) (in affirming dismissal of second complaint filed in same court in which motion for leave to amend was pending, court explained that a "trial court has discretion to dismiss a complaint which simply duplicates another pending related action"); *Oliney v. Gardner*, 771 F.2d 856, 859-60 (5th Cir. 1985) (where plaintiff "deliberately attempted to circumvent both local rule 2.5 of the Eastern District of Louisiana and Fed R. Civ. P. 15 by filing, and failing to inform the court or opposing counsel of a second identical lawsuit while the first lawsuit was still pending . . . the district court could properly dismiss the second suit as duplicative of the first, which was still pending."); *Clarke v. City of New York*, Nos. CV-96-5762(ERK), CV-98-7297(ERK), 1999 WL 608857, at *15 (E.D.N.Y. July 22, 1999) (where "the new complaint against Sergeant Repetti, arising out of the same events . . . is an effort to amend the initial complaint without the permission required by Fed. R. Civ. P. 15(a) [,] . . . the complaint against him would be subject to dismissal."); *Barapind v. Reno*, 72 F. Supp. 2d 1132, 1145 (E.D. Cal. 1999) (in dismissing second action after "Plaintiff did not seek to…amend [in first action]…under…Federal Rule of Civil Procedure Rule 15," court explained that "[a]lthough the number of claims have expanded, they all seek the same result"); *Fiore v. McDonald's Corp.*, Nos. CV-95-2708, 96-CV-0376, 1996 WL 331090, at *12 (E.D.N.Y. June 12, 1996) ("Because the complaint filed by the plaintiffs…involves identical parties and identical issues to a case already pending in this Court, the second complaint . . . must be dismissed.") (internal citation omitted); *Fawcett v. Ditkowsky*, No. 92 C 2371, 1992 WL 186065, at *3 (N.D. Ill. July 27, 1992) (dismissing duplicative action on ground that "Plaintiffs in effect propose an end-run around Federal Rule of Civil Procedure 15").

permission to add them. Biogen Opp. at 26. Nothing could be further from the truth. Even if the new claims are "supplemental" allegations governed by Rule 15(d), as plaintiffs suggest, they still must seek leave of court to assert them in this action. Fed. R. Civ. P. 15(d) ("Upon motion of a party, the court may, upon reasonable notice and upon such terms as are just, permit the party to serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented.")

There are two obvious reasons why Biogen and Genzyme failed to follow the proper procedure of filing a motion to amend, notwithstanding the Court's clear instructions at the September 9 hearing. First, they know that their newly asserted claims are defective on their face and that leave to amend would be denied. As just one example, Biogen and Genzyme purport to allege a claim for relief against Columbia styled as "abuse of process," even though Columbia has never served Biogen or Genzyme with any "process." *See Jones v. Brockton Public Markets, Inc.*, 369 Mass. 387, 390 (1975) ("in the context of abuse of process, 'process' refers to the papers issued by a court to bring a party or property within its jurisdiction," *e.g.*, a writ of attachment, the process used to initiate a civil action, and the process related to the bringing of criminal charges).

Second, Biogen and Genzyme desperately want this Court to issue an advisory opinion on their double patenting allegations, even though there is no case or controversy over their declaratory relief claims. Accordingly, they have sought to manufacture new claims solely as a pretext to include the allegation that the '275 patent is invalid and unenforceable. Of course, the Court carved out double patenting for expedited resolution because, until Columbia filed its Covenant, double patenting was a central, dispositive claim in each of the five actions consolidated in this multidistrict litigation. Double patenting is not, however, the central

dispositive issue in any of the four new claims that Biogen and Genzyme desire to assert, all of which have numerous other elements of proof. Nor have any of the other plaintiffs sought leave to file these new claims in any of their cases. To the extent the Court allows Biogen and Genzyme to file a proper supplemental pleading asserting these allegations, Columbia believes they can be resolved by dispositive motion without even considering the validity or enforceability of the '275 patent.

Columbia expects to file a motion to dismiss these claims on account of plaintiffs' failure to follow the applicable rules and the Court's express instructions. The Court should reject plaintiffs' suggestion that the double patenting phase of the case should continue, even if the declaratory relief claims are dismissed, in light of the defective new claims that plaintiffs have asserted through a flagrant violation of Rule 15.

I. Because Plaintiffs Have Obtained No Relief On The Merits From The Court, They Cannot Be A "Prevailing Party" For Purposes Of 35 U.S.C. § 285

Plaintiffs devote much effort to arguing that the Court still retains jurisdiction over their claims to recover attorneys' fees under 35 U.S.C. § 285, even if the Court dismisses their declaratory relief claims for lack of subject matter jurisdiction. Plaintiffs devote no effort to addressing the Supreme Court's controlling decision in *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't. of Health & Human Resources*, 532 U.S. 598 (2001), which requires the dismissal of their section 285 claims.

In *Buckhannon*, the United States Supreme Court held that the term "prevailing party" in federal fee-shifting statutes does not "authorize[ ] federal courts to award attorney's fees to a plaintiff who…has reached the 'sought-after destination' without obtaining any judicial relief." 532 U.S. at 601. Instead, the Supreme Court explained that, to "prevail," a party must "receive

at least some relief on the merits." *Id*. at 603 (quoting *Hewitt v. Helms*, 482 U.S. 755, 760 (1987)). The Supreme Court specifically noted that a *voluntary* change in the defendant's conduct which results in the plaintiff obtaining some of the relief it requested will *not* render the plaintiff a "prevailing party" for the purposes of attorneys' fees. *Id*. at 600. As the Supreme Court succinctly stated: "The question presented here is whether [the term 'prevailing party'] includes a party that has failed to secure a judgment on the merits or a court-ordered consent decree, but has nonetheless achieved the desired result because the lawsuit brought about a voluntary change in the defendant's conduct. We hold that it does not." *Id.*[17]

Here, plaintiffs have obtained no relief from this Court on the merits. With the dismissal of plaintiffs' declaratory judgment claims, this Court will have no opportunity to enter a "judgment on the merits or a court-ordered consent decree." Columbia's voluntary decision to grant plaintiffs a covenant not to sue "lacks the necessary judicial imprimatur" for plaintiffs to "prevail" under 35 U.S.C. § 285. *Buckhannon*, 532 U.S. at 601-02. The attorneys' fees claims should be dismissed.[18]

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[17] While *Buckhannon* did not involve section 285, the Federal Circuit recently noted, in reference to *Buckhannon* and its progeny, that "[t]he Supreme Court has interpreted the phrase 'prevailing party' consistently in all federal fee-shifting statutes." *Former Employees of Motorola Ceramic Products v. United States*, 336 F.3d 1360, 1363-64 (Fed. Cir. 2003); *see also Inland Steel Co. v. LTV Steel Co*., 364 F.3d 1318, 1320 (Fed. Cir. 2004) (citing, in the Section 285 context, *Motorola* and *Buckhannon* for "the general principle that to be a prevailing party, one must receive at least some relief on the merits, which alters…the legal relationship of the parties") (quotations omitted).

[18] J&J contends that the Covenant constitutes "a binding determination that it has no royalty obligation based on the existing claims of the '275 patent." J&J Opp. at 8. This is incorrect. The Covenant is not a "binding determination" of anything. It is a voluntarily filed document that has the legal effect of estopping Columbia from seeking any royalties from, or instituting an infringement action against, J&J based on the existing claims of the '275 patent with respect to erythropoietin, the one product covered by the parties' 1989 license agreement. *See Super Sack*, 57 F.3d at 1059 ("The legal effect of Super Sack's promise not to sue" creates

J. Plaintiffs' Arguments Regarding Remand Ignore The Realities Of The Few Remaining Claims That Do Not Turn On The Validity Or Enforceability Of The '275 Patent

Once all issues pertaining to the validity and enforceability of the '275 patent are removed from this litigation, only a few claims remain. Those claims—which are premised on specific contractual issues unique to a few of the plaintiffs—should be remanded to the courts from which they were transferred.

Plaintiffs simply ignore that the Judicial Panel on Multidistrict Litigation ("JPML") was explicit in describing the basis for transfer and pretrial consolidation of these cases. Specifically, the JPML transferred these cases to a single forum solely because of the common questions of fact raised by plaintiffs' claims that the '275 patent is invalid and unenforceable:

> [T]he Panel finds that the actions in this litigation involve common questions of fact. . . . At issue in each of the actions is the same patent, U.S. Patent No. 6,455,275 (the '275 patent) . . . Six of the actions and the potential tag-along action are brought against Columbia by pharmaceutical companies, each of which seeks a declaratory judgment of patent invalidity and unenforceability with respect to the '275 patent. The remaining action is brought by Columbia against two of those companies for breach of contract arising from license agreements relating to the '275 patent and for a declaratory judgment that the '275 patent is valid and enforceable. All actions can thus be expected to share factual and legal questions with respect to the '275 patent concerning patent validity and related questions such as double patenting, prosecution laches, and inequitable conduct.

In re Columbia Univ. Patent Litig., 313 F. Supp. 2d 1383, 1385 (J.P.M.L. 2004).

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an "estoppel [which], in turn, removes from the field any controversy sufficiently actual to confer jurisdiction over this case.").

In addition, J&J argues that many courts "have retained jurisdiction over a claim for fees under § 285 even after a covenant not to sue or voluntary dismissal has removed the court's jurisdiction over claims relating to infringement or validity." J&J Opp. at 7. All of the cases that J&J cites, however, were decided years before the Supreme Court's 2001 decision in *Buckhannon*.

Now that Columbia's Covenant has eliminated the validity and enforceability of the '275 patent as issues in this litigation, there is no sound reason for this Court to retain jurisdiction over those few claims that do not pertain to the '275 patent. And—despite some of the plaintiffs' protestations to the contrary—the few claims for which Columbia has requested suggestion of remand do not require resolution of the validity or enforceability of the '275 patent.

Columbia initially asked that the Court remand six claims—the only six claims that do not depend on a finding as to the validity or enforceability of the '275 patent. With J&J's admission that there is no longer a case or controversy with respect to its Fifth Claim for Relief, *see* J&J Opp. at 3, there are now only five claims to be remanded. One of these is Genentech's Fifth Claim for Relief. The other four are Columbia's counterclaims against Amgen and Immunex.

Genentech's Fifth Claim for Relief asserts that Columbia has improperly terminated Genentech's license agreement for "pretextual reasons" and that this improper termination constitutes a material breach of the Genentech license agreement. Notably, Genentech's failure to pay royalties on the '275 patent has been withdrawn as a basis for termination. Nevertheless, due to Genentech's failure to permit an audit as provided by the agreement, its license agreement remains terminated. What is left of Genentech's Fifth Claim for Relief—assuming that Genentech wishes to pursue this claim—does not and cannot turn on the '275 patent. Instead, questions of ordinary contract law and factual questions regarding Genentech's refusal to permit an audit will now determine the outcome of Genentech's contract claim. Moreover, as discussed above (*see* Section II.G.), to the extent that Genentech's Fifth Claim for Relief is premised on any argument that it is entitled to a return of royalties paid on the '275 patent, Columbia is willing to return such royalties.

Columbia has asserted counterclaims against Amgen and Immunex that are premised on the failure to pay royalties due under the original Axel patents, not the '275 patent. These counterclaims will not require the resolution of any issues related to the '275 patent, much less a decision on whether the '275 patent is valid and enforceable. Amgen does not assert otherwise, but instead argues that the remaining claims present "significant common questions." Amgen Opp. at 14. This is false. None of the claims brought by any of the other plaintiffs requires resolution of any issues relating to the predecessor Axel patents. This point is driven home by the fact that Amgen does not cite to any of the other claims that purportedly raise these "common" questions.

In short, plaintiffs' arguments in opposition to remand are specious. Once the claims pertaining to the '275 patent are dismissed, there will be no sufficient common questions of fact to justify the continued consolidation of pretrial proceedings in the Genentech and Amgen suits.

III. CONCLUSION

For the foregoing reasons, and those set forth in its moving papers, Columbia respectfully requests that the Court grant its Motion to Dismiss For Lack of Subject Matter Jurisdiction, and enter suggestion of remand as to any remaining claims.

September 28, 2004

Respectfully submitted,

THE TRUSTEES OF COLUMBIA
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